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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
SRIVASTAVA, KAILASH C	
ART UNIT	**PAPER NUMBER**
1655	

DATE MAILED: 07/27/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/088,664	HUANG ET AL.	
	Examiner	Art Unit	
	Dr. Kailash C. Srivastava	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 May 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 22-37 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 22-37 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *11.5.and 6.24.2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. The Art Unit Location to which your application has been assigned at the USPTO is changed to Art Unit 1655. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Examiner Kailash C. Srivastava in Art Unit 1655.

2. Request for continued examination (i.e., RCE) under 37 CFR §1.114, including the fee set forth in 37 CFR §1.17(e), was filed in this application on 11 May 2005 after a Final action mailed 13 July 2004. Since this application is eligible for continued examination under 37 CFR §1.114, and the fee set forth in 37 CFR §1.17(e) has been timely paid, the finality of the previous Office action mailed 13 July 2004 has been withdrawn pursuant to 37 CFR §1.114. Applicants' submission filed 11 May 2005 has been entered. ACCORDINGLY, an RCE has been established and the action on RCE follows.

3. Applicants' responsive Amendment filed 11 May 2005 is acknowledged and entered. The text of those sections of Title 35 U.S. Code not included in this action can be found in a prior Office action.

Applicants' Response to Rejections to Claims 1-21

4. In amendment filed 11 May 2005, applicants have cancelled Claims 1-21 that were drawn to a composition. In said amendment, applicants have filed new claims drawn to a method rather than to a composition as originally filed. Therefore, applicants' remarks/ arguments filed on 11 May 2005 in response to Final Office Action mailed 13 July 2004 wherein Claims 1-21 were either objected to or rejected under 35 U.S.C. §112, first and second paragraphs, 35 U.S. C. §1002(b) and 35 U.S. C. § 103(a) are moot. This is because criteria for patentability of newly presented Claims 22-37 is different than the criteria for originally presented Claims 1-21 drawn to a composition.

CLAIMS STATUS

5. Claims 1-21 have been cancelled.

6. Claims 22-37 have been added.

7. Claims 22-37 are pending and are examined on Merits.

Priority

8. Applicants' Claim of Priority to the filing date of 09/21/1999, the filing date for U.S. Provisional application No. 60/155, 018 under 35 U.S.C. §119 (e) and benefit date of 09/20/2000 which is the filing date for the PCT/US00/25733 under 35 U.S.C. §119 (a-d) is acknowledged. . Examiner has carefully

examined the disclosures and Claims presented in said priority Applications. However, applicants are not granted the priority date of 09/21/1999, or 09/20/2000. This is because the claimed subject matter presented in U.S. non-Provisional application referred *supra*, to which, the instant non-provisional Application and PCT application cited *supra* claim priority to has not been presented in said PCT application or currently under prosecution U.S. provisional application. Furthermore, currently under prosecution non-provisional U. S. application is a RCE filing, not a National Stage Application for said PCT application under 35 U.S.C. §371. Therefore, unless applicants can demonstrate to the contrary, the instant application is granted the benefit of the priority filing date of 08/15/2002, which is the filing date for the instant non-provisional U.S. application.

Information Disclosure Statement

9. Applicants' Information Disclosures (i.e., IDSs) filed 11 May 2005 and 24 June 2005 have been made of record. References A01 to C18, C20 to C31, C33-C46 and C48-C53 filed 11 May 2005 have been considered. References B30 and C54 in IDS filed 24 June 2005 have also been considered.

10. The information disclosure statement filed 11 May 2005 fails to comply with 37 CFR §1.98(a)(3) because References C19 and C32 in said IDS does not furnish, a concise explanation of the relevance, as it is presently understood by the individual designated in 37 CFR §1.56(c) most knowledgeable about the content of the information, of each patent listed that is not in the English language. It has been placed in the application file, but the information referred to therein has not been considered and that is why Examiner has not initialed said references. Applicants are requited to make appropriate correction

11. Reference C47 listed in said IDS filed 11 May 2005 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each U.S. and foreign patent; each publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. Reference C47 listed on said Form 1449 is incomplete. It has been placed in the application file, but the information referred to therein has not been considered and that is why Examiner has not initialed said reference. Applicants are requited to furnish a complete copy of said reference.

Double Patenting

12. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Long*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Omum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982);

In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR §1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 §CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR §3.73(b).

13. Claims 22-37 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 39, 43, 63 and 71-72 of Co-pending U.S. Patent Application No. 09/992,860. Although, conflicting claims are not identical, they are not patentably distinct from each other because claims 39, 43, 63 and 71-72 referenced U.S. Patent Application are drawn to a composition comprising the same ingredients and essentially the same steps to obtain a the method to treat/prevent colon cancer as claimed in the recited claims of instant application.

Claim Rejections Under 35 U.S.C. § 112

14. Claims 22-37 are rejected under 35 U.S.C.§112, first paragraph, because the specification, while enabling for a method to treat colon cancer via administering a composition comprising a mixture containing all the 14 components of orange peel extract (Specification, Page 4, Line 27 to Page 7, Line 21) or a mixture of tangeritin and nobeletin (Specification page, 7, Line 22 to Page 9, Line 7) or only resveratrol (See Page 12, Line 4 to Page 14, Line 19), does not reasonably provide enablement for a method to prevent colon cancer via instantly claimed method of administering the instantly claimed pharmaceutical composition comprising orange peel extract/ alleged all 14 components of orange peel extract in mixture with extracts of other plants, other phytochemicals or with resveratrol as claimed. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims because applicants have not demonstrated an example/ examples of entire scope of invention as claimed. Rather, applicants have merely made concluding assertions of their belief (see Page 9, Lines 8-13) to a method to treat colon cancer in humans via administering mixture(s) comprising orange peel extract components with a phytochemical compound obtained in extracts from other claimed plant species (e.g., rosemary extract or green tea extract), or with resveratrol/ resveratrol analog in food or dietary or nutraceutical supplements (e.g., Page 14, Lines 11-19).

Accordingly, undue experimentation without a reasonable expectation of success as to how to determine which combination of orange peel extract or components of orange peel extract with a

phytochemical compound in extracts of plants (e.g., Rosemary or Green tea) and/or resveratrol/ resveratrol analog in a physiologically acceptable carrier in which therapeutic amounts of any or all of the claimed designated components would be effective in the instantly claimed method to administer the instantly claimed composition to obtain the instantly claimed functional effect of treating cancer and which type of cancer would be required to practice the invention as claimed due to the quantity of experimentation necessary; limited amount of guidance and limited number of working examples in the specification; nature of the invention; state of the prior art; relative skill level of those in the art; predictability or unpredictability in the art; and breadth of the claims. In re Wands, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988). The quantity of undue experimentation would be necessary because applicants have not demonstrated a cumulative/ synergistic effect of claimed compositions/mixtures of claimed components with a pharmaceutical carrier/excipient. There is no guidance in what proportions those various components from orange peel extract will be mixed with each other or with other phytochemical extracts (e.g., Rosemary or black tea extracts) and no examples are furnished.

15. Claims 23-37 are rejected under 35 U.S.C.§112, first paragraph, because the specification, while enabling for a method to administer composition comprising claimed orange peel extract components or resveratrol extract to treat colon cancer (See Page 5, Line 7 to Page 7, Line 25 and Page 13, Lines 1-14), does not reasonably provide enablement for a method to treat and/or prevent colon cancer via instantly claimed method of administering a mixture comprising all the fourteen components isolated from orange peel extract or orange peel extract components with other phytochemicals extracted in extracts obtained in resveratrol or rosemary or black tea or Huzhang extract (See specification , Page 5, Line 7 to Page 7, Line 25; Page 9, Lines 8-13; Page 13, Lines 1-15; Page 13, Line 21 to Page 14, Line 14). The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims. Thus, the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

Inventions targeted for human therapy claiming method(s) of prevention of a certain ailment, especially cancer bear a heavy responsibility to provide supporting evidence because of the unpredictability of the biological responses to therapeutic treatments. THE STANDARD OF ENABLEMENT IS HIGHER FOR SUCH INVENTIONS because effective treatment and/or prevention or prophylaxis of disease conditions are relatively rare, and may be unbelievable in the absence of supporting evidence. Claims drawn to pharmaceutically acceptable compositions and to methods of administering compounds to human that would in effect "prevent" the condition/ailment from happening require supporting evidence because of the unpredictability in biological responses to therapeutic treatments or therapeutic prophylaxis. In order to enable the skilled artisan to practice the invention as claimed, applicants would

have to demonstrate the functional effect and describe the therapeutic effect or prophylactic effect, and describe the effective amounts of each ingredient of the composition for the administration of said composition intended for a method of therapeutic treatment or prophylaxis. THERE IS NO GUIDANCE IN THE SPECIFICATION, other than a method to administer a composition comprising a mixture of phytochemicals/plant extracts to treat/prevent cancer. MOREOVER, THE INSTANT APPLICATION DOES NOT PROVIDE A WORKING EXAMPLE PROVIDING DATA THAT SHOWS THAT THE METHOD AND COMPOSIOTION OF THE INSTANTLY CLAIMED INVENTION WOULD INDEED PREVENT AN EVENT SUCH AS THE CLAIM DESIGNATED DISEASE CONDDITIONS. THUS, APPLICANTS HAVE NOT DEMONSTRATED THE CLAIMED FUNCTIONAL EFFECT OF PREVENTING Colon Cancer.

Accordingly, undue experimentation without a reasonable expectation of success as to how to determine which combination of each of the claimed ingredients or a pharmaceutically acceptable composition" in mixtures with one of the components of the orange peel extract or all of the components of the orange peel extract in combination with resveratrol, resveratrol analog, rosemary extract, black tea extract or Huzhang extract with a pharmaceutically acceptable carrier in which therapeutic amounts of any or all of the claimed designated components would be effective in the instantly claimed method to administer the instantly claimed composition to obtain the instantly claimed functional effect of treating and/or preventing colon cancer in a human would be required to practice the invention as claimed due to the quantity of experimentation necessary; limited amount of guidance and limited number of working examples in the specification; nature of the invention; state of the prior art; relative skill level of those in the art; predictability or unpredictability in the art; and breadth of the claims. In re Wands, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

16. Claims 22-37 are rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- Phrase "such that" renders claims 22-23 vague, unclear and therefore, indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

- The phrase, "in a reduction in" renders claim 24 unclear, vague and therefore, indefinite. This phrase is indefinite because it is not clear as to presence of aberrant crypt or aberrant crypt foci are reduced with reference to another treatment, with reference to those found in a normal animal or those found in a cancerous cell or those found in a patient having a colon cancer or what? The metes and bounds for the phrase "in a reduction in" are not defined. Therefore, an artisan will not be apprised of the phrase "in a reduction in".

Examiner reminds the applicants that although claims are read in light of the specification, the specification language cannot be read in the claims to ascertain what is being claimed or claimed subject matter. Applicants have to clearly define the subject matter that applicants are claiming or intend to claim within the claim language. Examiner suggests that the applicants define the metes and bounds for the phrase "in a reduction in" within the claim.

- Phrases, "20-50μg/ml", "5000 ppm supplement of the human's diet", "0.2% of the human's diet" in Claims 25, 28-29 and 31-33 render those claims unclear. Vague and therefore indefinite because for example what is meant by the phrase "20-50μg/ml"? of a composition, if so what is the composition? a beverage an elixir, or what? Furthermore, is that amount administered only once a day or, how many times or at what frequency during what time per day, per week per month or per year? Applicants clearly need to define the dosage in art –known dosage term, e.g., "20-50μg/ml" of a beverage, wherein the individual is administered 500 mL of a composition comprising said beverage 6 times every 24 hours. Alternatively, 5000 ppm per Kg or 0.2%/ Kg of individual's daily diet administered 3 times per 24 hours.

- Claim 37 is rendered vague and indefinite because of the term "extract". This term, in and of itself, does not adequately delineate its metes and bounds. This term is best defined as a product-by process since product-by-process claims are intended to define products that are otherwise difficult to define (and/or distinguish from the prior art). For example, from what part(s) of the plant is the extract obtained? It is well accepted in the herbal art that extraction with one of various distinct solvents, as well as from particular parts of therapeutic plants, has a profound impact on the final product with respect to the presence, absence, amounts, and/or ratios of active ingredients therein and, thus, its ability to provide the necessary functional effect(s) instantly claimed and/or disclosed. Since the extract itself is clearly essential to the claimed invention, the steps(s) by which the claimed extract is obtained are also clearly essential and, therefore, must be recited in the claim language itself (i.e., as a product-by-process). Please note that although claims are interpreted in light of the specification, critical limitations from the specification cannot be read into the claims (see, e.g., *In re* Van Guens, 988 F.2d 1181, 26 PSPG2d 1057 (DED. Cir. 1991). Accordingly, without the recitation of all these critical limitations as set forth above, the cited claims do not adequately define the instant invention.

All other claims depend directly/indirectly from the rejected claims (e.g., Claim 22 or 23) and are, therefore, also rejected under 35 U.S.C. §112, second paragraph for the reasons set forth above.

Claim Rejections – 35 U.S.C. § 102

17. Claims 22-24 are rejected under 35 U.S.C. §102(b) as anticipated by Xu et al (European Journal of Cancer Prevention, Volume 2, 1993, Pages 327-335).

Claims recite a method to treat/ prevent colon cancer and reduce the presence of aberrant crypt or aberrant crypt foci when a composition comprising a mixture of 14 flavonoids isolated from orange peel was administered to a human in need of said treatment.

Xu et al. teach treating colon cancer as manifested by reduction in the quantities of urinary excretion of N-nitrosoproline (NPRO) in subjects treated with orange peel powder in contrast to those that were not given equivalent of 75 mg/ day of vitamin C as orange peel powder (Figure 3, Page 331, Column 2, Lines 1-112 under Figure 2). The equivalent orange peel powder dosage was 6 g Orange peel powder/day. Note that Occurrence of N-nitroso- compounds (NOC) represented by NPRO has been confirmed as increased colon cancer risk among other types of cancer (Page327, Column 2, Line32 to Page 328, Column 1, Line 4). Note that administering orange peel powder essentially is administering each and every one of the 14 flavonoids isolated from orange peel to the subjects in Xu et al's study. Even though Xu et al. do not explicitly disclose prevention/ reduction in aberrant crypt or aberrant crypt foci, prevention of colon cancer and reduction in aberrant crypt or aberrant crypt foci because of administering said orange peel powder to an individual, the claims are anticipated by the Examiner-cited prior art reference because the functional intended use of a composition does not materially change a composition and is accordingly, not given any patentable weight. Furthermore, administration of said 6 g/day dosage of orange peel powder would upon its ingestion by an individual inherently have an effect by the same index as is recited in the claimed invention because the quantity of composition administered to obtain the intended effect is not clearly recited in the claims. Therefore, the prior art method (i.e., administering 6 g/ day orange peel powder) inherently must function as claimed because the said prior art composition is comprised of same components and is being administered in the same way as the claimed method (See e.g., In re Best, 195 USPQ 430, 433-CCPA 1977).

Therefore, the reference is deemed to anticipate the cited claims.

Claims Rejections Under 35 U.S.C §103(a)

18. Claims 22-37 are rejected under 35 U.S.C. § 103 (a) as obvious over combined teachings from Xu et al (European Journal of Cancer Prevention, Volume 2, 1993, Pages 327-335) in view of Bailey et al (U.S. Patent 5,859,293), Madis Botanicals (Madis Botanicals, Inc., Resverapure™ Resveratrol PE 8%, Product Code 04544, Page 2, Lines 6-7 and 15-31, 1997) and Castleman (The Healing Herbs, The Ultimate Guide to the Curative Power of Nature's Medicines, 1991, Rodale Press, Emmaus, PA. Page 349, Column 2, Lines 3-10).

(a) Claims recite a method to treat/ prevent colon cancer and reduce the presence of aberrant crypt or aberrant crypt foci when a composition comprising a mixture of 14 flavonoids isolated from orange peel mixed with resveratrol, hydroxylated analogs of resveratrol, methoxylated analogs of resverattrol, rosemary extract, black tea extract, Mexican bamboo extract or a Huzhang Extract, wherein 14 orange peel flavonoid component mixture is administered at a dosage of "20-50μg/ml, 5000 ppm supplement of the human's diet, 0.2% of the human's diet".

Teachings from Xu et al. have already been discussed *supra.* Xu et al., however, do not disclose other plant extracts (claimed in Claim 37) for treating/preventing colon cancer.

Bailey et al., (Column1, Lines 29-34 and Column 2, Lines 10-15) teach inhibition or delayed onset of certain types of cancers when extracts from rosemary and other plants are ingested. Madis Botanicals (Page 2, Column 1, Lines 6-7 and 15-31) teaches powdered nutraceutical and dietary supplement preparations of resveratrol obtained from Huzhang or knotweed to inhibit carcinogenesis or tumerogenesis. Madis Botanicals also discloses that Huzhang or knotweed or Mexican bamboo or giant knotwood are all *Polyganum cuspidatum* and resveratrol is an antioxidant obtained from this plant species. Castleman teaches that black tea has antioxidants and therefore, it may also be helpful in cancer prevention. All the references cited also disclose that the plant extracts cited herein are comprised of antioxidants and it is the antioxidant component of these plants that is effective in either inhibiting or late onset of different types of cancer.

A person of ordinary skill in the art at the time the invention was made would have been motivated to combine the teachings from different prior art references cited *supra* to obtain a method comprising administration of a composition comprising orange peel powder mixed with resveratrol, hydroxylated analogs of resveratrol, methoxylated analogs of resverattrol, rosemary extract, black tea extract, Mexican bamboo extract or a Huzhang extract, wherein 14 orange peel flavonoid component mixture is administered to an individual in need thereof to treat colon cancer because all of the prior art

references (Xu et al., Bailey et al., and Madis Botanicals) teach inhibition or delayed onset of cancers when compositions comprising orange peel, and extracts from rosemary, Huzhang, Mexican bamboo and composition containing resveratrol (a compound obtained from Huzhang) are ingested by a mammal in need thereof. Bailey et al. remedy the deficiency in Xu et al's method of rosemary extract having anticarcinogenic property, Castelman remedies in Xu et al's method the deficiency of the anticarcinogenic property in tea and Madis Botanicals remedies in Xu et al's method the deficiency of resveratrol or Huzhang, or Mexican bamboo. The prior art references cited above do not teach the same dosage of orange peel components as claimed instantly or to administer it in a certain form (e.g., tablet, liquid, or capsule) However, the adjustment of particular conventional working conditions (e.g., mode or form of administration of a composition or dosage of composition to treat a certain disease) is deemed merely a matter of judicious selection and routine optimization of a result-effective parameter that is well within the purview of the skilled artisan.

Thus, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the claimed invention was made to combine the instant ingredients (i.e., orange peel mixed with resveratrol, hydroxylated analogs of resveratrol, methoxylated analogs of resveratrol, rosemary extract, black tea extract, Mexican bamboo extract or a Huzhang Extract, wherein 14 orange peel flavonoid component mixture for their known benefit since each ingredient is well known in the art for the same purpose) in a composition and administer said composition in a method to treat colon cancer. This rejection is based on the well established proposition of patent law that no invention resides in combining old ingredients of known properties where the results obtained thereby are no more than the additive effect of the ingredients, *In re Sussman,* 1943 C.D. 518. Applicants invention is predicated on an unexpected result, which typically involves synergism, an unpredictable phenomenon, highly dependent upon specific proportions and/or amounts of particular ingredients. Any mixture of the components embraced by the claims which does not exhibit an unexpected result (e.g., synergism) is therefore *ipso facto* unpatentable.

Accordingly, the instant claims, in the range of proportions where no unexpected results are observed, would have been obvious to one of ordinary skill having the above-cited references before him.

From the teachings of the cited references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Conclusion

19. For reasons aforementioned, no Claims are allowed.

20. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Kailash C. Srivastava whose telephone number is (571) 272-0923. The examiner can normally be reached on Monday to Thursday from 7:30 A.M. to 6:00 P.M. (Eastern Standard or Daylight Savings Time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Bruce Campell, can be reached on (571)-272-0974 Monday through Friday 8:00 A.M. to 4:30 P.M. The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding may be obtained from the Patent Application Information Retrieval (i.e., PAIR) system. Status information for the published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (i.e., EBC) at: (866)-217-9197 (toll-free). Alternatively, status inquiries should be directed to the receptionist whose telephone number is (703) 308-0196.

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July 25, 2005

RALPH GITOMER
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